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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,192	06/23/2006	Takayuki Oniki	0171-1287PUS1	3847
2292 7590 05/02/2011 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER SUTTON, DARRYL C				
ART UNIT 1612		PAPER NUMBER		
NOTIFICATION DATE 05/02/2011		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/584,192

Applicant(s)

ONIKI ET AL.

Examiner

DARRYL C. SUTTON

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23, 24, 26, 27, 30-32, 34, 35, 38, 39 and 41-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 24, 26, 27, 30-32, 34, 35, 38, 39 and 41-58 is/are rejected.
- 7) ☒ Claim(s) 44-58 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the amendment filed 02/21/2011. New claims 43-58 have been added.

Applicant's arguments filed 02/21/2011 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Objections

Claims 44-58 are objected to because of the following informalities: the word "tooth" in line 1 of claim 44 should be "a tooth" or "teeth". The term "a peroxide" in line 18 of claim 49 is repetitive, since the limitation pertaining to "a peroxide" has already been cited in line 16. The term "keeping long" in line 1 of claims 54-58 should be "lengthening." The term "an enamel" in lines 22 of claim 49, should be "enamel." There should be an "a" between the words "of" and "tooth whitening set" in line 3 of claim 54.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23, 24, 26, 27, 30-32, 34, 35, 38, 39 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patacca et al. (US 2004/0102554) in view of Oniki et al. (WO 03/030851).

Patacca et al. discloses easily removable film forming compositions for coating teeth to provide a cosmetic coating of undesirable appearing teeth; the coating does not alter the tooth in any way, except the color and is reversible (Abstract, [0001], [0005], [0015] and [0017]). The composition is comprised of the claimed substance (A) in amounts of about 60% to about 90%; substance (B) in amounts of about 10%; and substance (C) in amounts of about 1% [0008] - [0010]. The application device for the composition is not critical [0016].

Patacca et al. do not teach that the composition is applied to the teeth with a detachably fit tool or times of application.

Oniki et al. teaches a method of making teeth look whiter by causing a whitening component to infiltrate into the tooth enamel, thereby changing the optical properties of the enamel without chemical reactions (page 1, lines 8-15 and page 2, lines 33-37). Whitening components, i.e. substance A, are taught which are substantially the same

compounds as those of Patacca in amounts of 20% to 100% (page 4, lines 15-29 and page 5, lines 19-20). Gelling agents, i.e. substance (C), which are substantially the same as those of Patacca in amounts of from 0.1% to 15% are taught (page 6, lines 8-13). The whitening component is applied to teeth in concert with a special tool, such as tapes, sheet or films, which retains and keeps it in position in contact with teeth, prevents the composition from dissolving and dilution by saliva and eliminates unpleasant feeling. The tools are formed from materials such as polyethylene, foamed polyethylene, polypropylene, polyester, rayon, pulp, cotton, silk and paper (page 8, lines 24-36 and page 9, lines 13-15). The duration of application is 1 to 120 minutes per dosage (page 10, lines 9-12). Oniki et al. do not teach a composition that is further comprised of the substance (B) of instant claims 23, 26, 31, 34, 39, 41 and 42.

At the time of the invention, it would have been obvious to modify the composition of Patacca et al. to be applied with the tools and for the times of Oniki et al. discussed *supra* since the compositions are substantially the same and the tools of Oniki et al. would help to retain the compositions in contact with the teeth, eliminate unpleasant feeling and excess salivation, and detachment from teeth by occlusion and chewing as taught by Oniki et al., page 8, lines 24-32 and since Patacca et al. teaches that there is no restriction on the application device and that the coating composition is retained in contact with teeth.

Since Oniki et al. teach that substance (A) is a whitening component which infiltrates tooth enamel and changes its optical properties, substance (B), which is also dissolved in the solvent of the composition would reasonably be expected to also

infiltrate the enamel in addition to providing a coating on the surface of the teeth. The effect of saliva on the components of the composition would be inherent on the specific components. Accordingly, the components of Patacca et al. which are substantially the same components as those of the instant claims would reasonably be expected to be precipitated by saliva. And, the composition would reasonably be expected to change the optical properties of teeth when applied for the times and with the tools of Oniki et al.

Claims 44-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oniki et al. (WO 03/030851) in view of Takeda et al. (US 2001/0007652) as evidenced by Sharma et al. (Def. Sci. J., 1983).

Oniki et al. is discussed *supra*.

Oniki et al. does not teach that the composition is further comprised of a substance (B).

Takeda et al. teach a dentifrice composition for imparting gloss on teeth comprising shellac; when the composition is used the whiteness inherent in teeth can be given to the teeth, and good gloss, brightness and luster can be further imparted on teeth due to the prevention of the irregular reflection of light by a coating of shellac (Abstract, [0039]), i.e. shellac changes the optical properties of teeth. The composition can be in the form of a gel [0007], [0016]. The content of shellac is 0.01% to 10% [0013]. The composition comprises propylene glycol and/or glycerin [0018]. Thickening agents such as sodium carboxymethylcellulose are used in the compositions [0017].

The shellac is dissolved in conventional dentifrice substances such as propylene glycol [0018]. Foaming agents such as sodium lauryl sulfate may be included in the composition in amounts of 1.5% by weight [0017] and [0025]. No particular limitation is imposed on the usage of the dentifrice compositions [0019]. As evidenced by Sharma et al., shellac is comprised of gallic acid and gallic acid, i.e.

9,10,16-trihydroxypalmitic acid with ester or lactone linkage, page 262, last paragraph.

Takeda et al. does not teach the specific amount of propylene glycol.

Takeda et al. does not teach the specific amount of propylene glycol.

Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Accordingly, it would have been obvious to combine the shellac in the weight ratios of Takeda with the composition of Oniki et al. in order to form a third solution that also changes the optical properties of teeth and makes teeth appear white.

At the time of the invention, it would have been obvious to modify the composition to be comprised of propylene glycol as the whitening agent, since Takeda et al. teach that the shellac is dissolved in propylene glycol when producing the composition, and Oniki et al. teach its incorporation as the whitening agent. It would assure that the shellac is dissolved as required by Takeda et al., which would allow it to infiltrate into the tooth enamel along with the propylene glycol, thereby changing the optical properties of the enamel as taught by Oniki et al.

In regards to claims 44, 49 and 54, the prior art does not teach the specific amounts of the tooth whitening ingredient, A. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Oniki et al. teach from 20% to 100% of the whitening ingredient versus 50.0 to 99.5% of the instant claims.

Since the compositions suggested by combining Oniki et al. and Takeda et al. are utilized for making teeth look whiter, it would have been obvious to apply them to teeth. Since the shellac forms a film on the teeth, it would reasonably be expected to lengthen the time in which the whitening substance of Oniki et al. is able to change the optical properties of teeth.

Applicant's arguments

Applicant argues that even though Oniki and Takeda disclose a method for making teeth look white, Oniki uses irregular reflection and Takeda uses regular reflection. Takeda's tooth whitening action is completely opposite of Oniki's method. The skilled artisan would not combine the references to achieve the present invention. At least some degree of predictability is required.

The Examiner disagrees.

Although the methods utilize different measurements of light, this would not deter the skilled artisan from using them together. The combination of Oniki et al. and

Takeda et al. would result in the predictable result of the enamel whitening of Oniki et al. along with the whitening and high gloss effect of Takeda et al. Further, as discussed *supra*, the shellac of Takeda et al. would be expected provide a benefit of lengthening the time in which the whitening substance of Oniki et al. is inside the tooth enamel, which would provide further motivation to the skilled artisan. Accordingly, the film of Takeda et al. would reasonably be expected to provide its effect on the appearance of teeth and once the film wears off, the whitening substance of Oniki et al. would still remain in the tooth enamel and continue to change the optical properties of the enamel and make teeth look white, i.e. the length of the whitening effect would be prolonged.

Applicant argues that reconsideration of the previously submitted declaratory is requested in light of the new set of claims.

The Examiner disagrees.

In light of the new claims, the Examiners response submitted on 10/01/2010 to Applicant's Declaration which was submitted on 08/17/2010 is still applicable, see pages 11-13.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612